

PACKAGE LEAFLET

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Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

PegIntron 50 micrograms powder and solvent for solution for injection in pre-filled pen
Peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 50 micrograms/0.5 ml.
- The other ingredients are:
Powder: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80;
Solvent: water for injections

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR

The pharmaceutical form is: powder and solvent for solution for injection.

The powder and solvent are both contained in a two-chamber glass cartridge assembled into a single use pre-filled pen.

PegIntron 50 micrograms is available in different pack sizes:

- 1 pen containing powder and solvent for solution for injection, 1 injection needle and 2 cleansing swabs;
- 4 pens containing powder and solvent for solution for injection, 4 injection needles and 8 cleansing swabs;
- 6 pens containing powder and solvent for solution for injection, 6 injection needles and 12 cleansing swabs;
- 12 pens containing powder and solvent for solution for injection, 12 injection needles and 24 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

2. BEFORE YOU USE PEGINTRON

PegIntron is not recommended for use in patients under the age of 18 years.

Do not use PegIntron:

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

Take special care with PegIntron:

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

Driving and using machines:

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE PEGINTRON

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

Combination treatment

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

PegIntron alone:

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

All patients:

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to use the PegIntron pre-filled pen).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. PegIntron is intended for single use only. Thus, after you give yourself the injection, discard the PegIntron pre-filled pen with any solution that is left in it.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

If you use more PegIntron than you should:

Tell your doctor or healthcare professional as soon as possible.

If you forget to take PegIntron:

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; convulsion ("fit"); trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyes or your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PEGINTRON

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the reconstituted solution.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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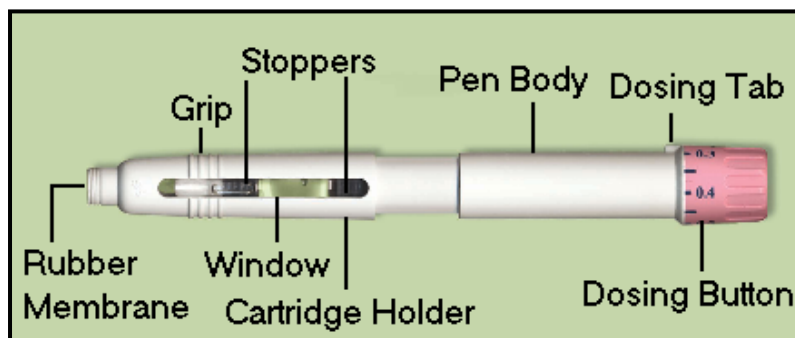
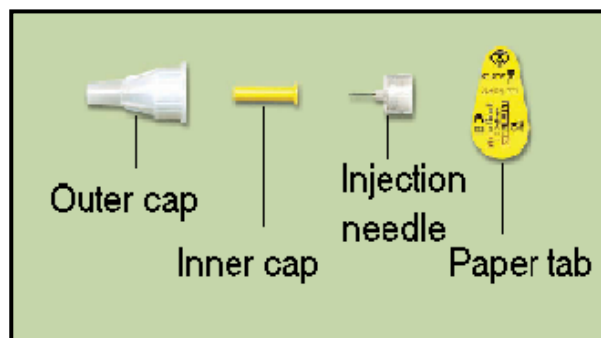
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This leaflet was last approved on

ANNEX TO THE PACKAGE LEAFLET

How to use the PegIntron pre-filled pen



The following instructions explain how to inject yourself with the single use PegIntron pre-filled pen. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you on how to self-inject with the PegIntron pre-filled pen. Do not attempt to inject yourself unless you are sure you understand the procedure and requirements for self-injection.

The PegIntron pre-filled pen is intended for use by one person only and must not be shared. Use the injection needle and cleansing swabs provided in the packaging only for the PegIntron pre-filled pen. Be sure the solution is at room temperature at the time of injection. Your doctor will have told you what dose you require for your therapy.

Note: The colour of the dosing button is different for each strength of the PegIntron pre-filled pen.

Step 1: Mixing

It is important that you keep the PegIntron pre-filled pen upright (as shown in figure 1) during mixing, unless otherwise instructed.

- Take the PegIntron pre-filled pen out of the refrigerator. Allow the medicine to come to room temperature.



Figure 1

- Wash your hands with soap and water.
- **Place the PegIntron pre-filled pen upright** in the holder of the tray provided in the pack (the dosing button will be on the bottom).
- You may want to hold the pre-filled pen using the grip. To mix the powder and the liquid, press the two halves together firmly by pressing down until you hear the pre-filled pen click. The two stoppers should come together.
- Wait for several seconds until the powder is completely dissolved.
- **Gently turn the PegIntron pre-filled pen upside down twice. To avoid excessive foaming, do not shake.**
- Maintaining the PegIntron pre-filled pen upright, check the mixed PegIntron solution through the window. If there is still foam, wait until it settles. **Do not use the pen if the solution is discoloured or contains any particles.**



- Keeping the PegIntron pre-filled pen upright in the holder provided in the packaging, disinfect the rubber membrane of the PegIntron pre-filled pen with one cleansing swab.
- Remove the protective paper tab from the injection needle.
- **Maintaining the PegIntron pre-filled pen upright in the holder**, gently push the injection needle onto the pre-filled pen and screw it securely in place.

Figure 2

- **Keep the PegIntron pre-filled pen pointed up.**
- **Do not take off the outer needle cap at this point.**
- You may see some liquid trickle out from under the cap, as the air has been expelled out of the pen.
- Wait about 5 seconds for this process to finish.



- **Check through the window to be sure that the two stoppers are together. If they are not together, do not use this pen because you may not be able to dial your dose.**

Figure 3

Step 2: Setting the dose



- Remove the PegIntron pre-filled pen from the holder.
- Holding the PegIntron pre-filled pen firmly, pull the dosing button out as far as it will go, until you see a dark ring on the pen. The dosing button should be easy to pull out without excessive force being required.

Note: Do not push the dosing button back in at this time. You will push it in when you are ready to self-inject the PegIntron.

Figure 4



Figure 5

- Turn the dosing button until your prescribed dose is aligned with the dosing tab. The button should turn easily without excessive force being required.

Note: If you cannot easily pull out the dosing button or dial the dose, do not use excessive force and do not use this pen because it may not deliver the correct dose.

Step 3: Injecting the solution

- Select the injection site. Your doctor will have told you which sites to use (e.g., thigh or abdomen).

Note: change your injection site each time.

- Clean the injection site skin with the second cleansing swab.



Figure 6

- Pull off the outer needle cap.
- There may be some liquid around the inner needle cap. This liquid is not part of your dose, this is extra. This is normal, as the air has been expelled out of the needle.
- Once the injection site is dry, pull off the inner needle cap carefully exposing the injection needle.



Figure 7

- Hold the PegIntron pre-filled pen with your fingers wrapped around the barrel and your thumb on the dosing button.
- With your other hand, pinch a fold of loose skin.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until the button can no longer move.
- Maintain pressure on the dosing button for an additional 5 seconds to ensure that you get the complete dose.

- Remove the needle from your skin.
- Press the injection site with a small bandage or sterile gauze if necessary for a few seconds.
- Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.
- Discard the PegIntron pre-filled pen with the needle safely in a closed rigid container.

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- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
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6. Further information

PegIntron 80 micrograms powder and solvent for solution for injection in pre-filled pen
Peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 80 micrograms/0.5 ml.
- The other ingredients are:
Powder: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80;
Solvent: water for injections

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR

The pharmaceutical form is: powder and solvent for solution for injection.

The powder and solvent are both contained in a two-chamber glass cartridge assembled into a single use pre-filled pen.

PegIntron 80 micrograms is available in different pack sizes:

- 1 pen containing powder and solvent for solution for injection, 1 injection needle and 2 cleansing swabs;
- 4 pens containing powder and solvent for solution for injection, 4 injection needles and 8 cleansing swabs;
- 6 pens containing powder and solvent for solution for injection, 6 injection needles and 12 cleansing swabs;
- 12 pens containing powder and solvent for solution for injection, 12 injection needles and 24 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

2. BEFORE YOU USE PEGINTRON

PegIntron is not recommended for use in patients under the age of 18 years.

Do not use PegIntron:

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

Take special care with PegIntron:

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

Driving and using machines:

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE PEGINTRON

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

Combination treatment

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

PegIntron alone:

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

All patients:

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to use the PegIntron pre-filled pen).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. PegIntron is intended for single use only. Thus, after you give yourself the injection, discard the PegIntron pre-filled pen with any solution that is left in it.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

If you use more PegIntron than you should:

Tell your doctor or healthcare professional as soon as possible.

If you forget to take PegIntron:

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; convulsion ("fit"); trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyes or your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PEGINTRON

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the reconstituted solution.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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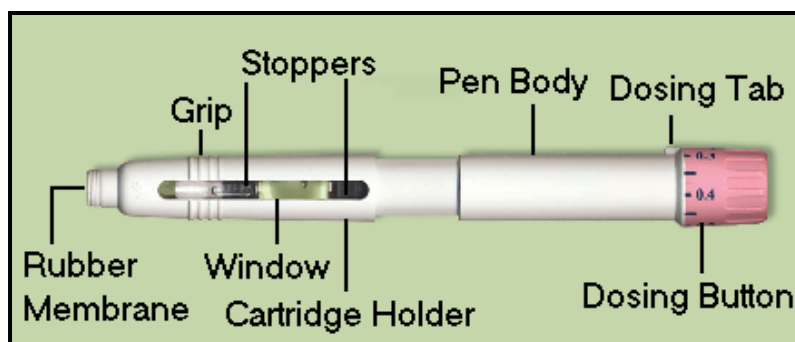
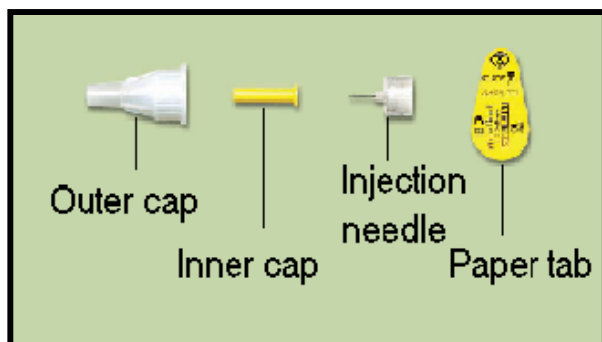
Italia

Centro Direzionale Milano Due
Palazzo Borromini
I-20090 Segrate (Milano)
Tel: + 39-02 21018.1

This leaflet was last approved on

ANNEX TO THE PACKAGE LEAFLET

How to use the PegIntron pre-filled pen



The following instructions explain how to inject yourself with the single use PegIntron pre-filled pen. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you on how to self-inject with the PegIntron pre-filled pen. Do not attempt to inject yourself unless you are sure you understand the procedure and requirements for self-injection.

The PegIntron pre-filled pen is intended for use by one person only and must not be shared. Use the injection needle and cleansing swabs provided in the packaging only for the PegIntron pre-filled pen. Be sure the solution is at room temperature at the time of injection. Your doctor will have told you what dose you require for your therapy.

Note: The colour of the dosing button is different for each strength of the PegIntron pre-filled pen.

Step 1: Mixing

It is important that you keep the PegIntron pre-filled pen upright (as shown in figure 1) during mixing, unless otherwise instructed.

- Take the PegIntron pre-filled pen out of the refrigerator. Allow the medicine to come to room temperature.



Figure 1

- Wash your hands with soap and water.
- **Place the PegIntron pre-filled pen upright** in the holder of the tray provided in the pack (the dosing button will be on the bottom).
- You may want to hold the pre-filled pen using the grip. To mix the powder and the liquid, press the two halves together firmly by pressing down until you hear the pre-filled pen click. The two stoppers should come together.
- Wait for several seconds until the powder is completely dissolved.
- **Gently turn the PegIntron pre-filled pen upside down twice. To avoid excessive foaming, do not shake.**
- Maintaining the PegIntron pre-filled pen upright, check the mixed PegIntron solution through the window. If there is still foam, wait until it settles. **Do not use the pen if the solution is discoloured or contains any particles.**



Figure 2

- Keeping the PegIntron pre-filled pen upright in the holder provided in the packaging, disinfect the rubber membrane of the PegIntron pre-filled pen with one cleansing swab.
- Remove the protective paper tab from the injection needle.
- **Maintaining the PegIntron pre-filled pen upright in the holder**, gently push the injection needle onto the pre-filled pen and screw it securely in place.

- **Keep the PegIntron pre-filled pen pointed up.**
- **Do not take off the outer needle cap at this point.**
- You may see some liquid trickle out from under the cap, as the air has been expelled out of the pen.
- Wait about 5 seconds for this process to finish.



Figure 3

- **Check through the window to be sure that the two stoppers are together. If they are not together, do not use this pen because you may not be able to dial your dose.**

Step 2: Setting the dose



Figure 4

- Remove the PegIntron pre-filled pen from the holder.
- Holding the PegIntron pre-filled pen firmly, pull the dosing button out as far as it will go, until you see a dark ring on the pen. The dosing button should be easy to pull out without excessive force being required.

Note: Do not push the dosing button back in at this time. You will push it in when you are ready to self-inject the PegIntron.



Figure 5

- Turn the dosing button until your prescribed dose is aligned with the dosing tab. The button should turn easily without excessive force being required.

Note: If you cannot easily pull out the dosing button or dial the dose, do not use excessive force and do not use this pen because it may not deliver the correct dose.

Step 3: Injecting the solution

- Select the injection site. Your doctor will have told you which sites to use (e.g., thigh or abdomen).

Note: change your injection site each time.

- Clean the injection site skin with the second cleansing swab.



Figure 6

- Pull off the outer needle cap.
- There may be some liquid around the inner needle cap. This liquid is not part of your dose, this is extra. This is normal, as the air has been expelled out of the needle.
- Once the injection site is dry, pull off the inner needle cap carefully exposing the injection needle.



Figure 7

- Hold the PegIntron pre-filled pen with your fingers wrapped around the barrel and your thumb on the dosing button.
- With your other hand, pinch a fold of loose skin.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until the button can no longer move.
- Maintain pressure on the dosing button for an additional 5 seconds to ensure that you get the complete dose.

- Remove the needle from your skin.
- Press the injection site with a small bandage or sterile gauze if necessary for a few seconds.
- Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.
- Discard the PegIntron pre-filled pen with the needle safely in a closed rigid container.

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

PegIntron 100 micrograms powder and solvent for solution for injection in pre-filled pen
Peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 100 micrograms/0.5 ml.
- The other ingredients are:
Powder: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80;
Solvent: water for injections

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR

The pharmaceutical form is: powder and solvent for solution for injection.

The powder and solvent are both contained in a two-chamber glass cartridge assembled into a single use pre-filled pen.

PegIntron 100 micrograms is available in different pack sizes:

- 1 pen containing powder and solvent for solution for injection, 1 injection needle and 2 cleansing swabs;
- 4 pens containing powder and solvent for solution for injection, 4 injection needles and 8 cleansing swabs;
- 6 pens containing powder and solvent for solution for injection, 6 injection needles and 12 cleansing swabs;
- 12 pens containing powder and solvent for solution for injection, 12 injection needles and 24 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

2. BEFORE YOU USE PEGINTRON

PegIntron is not recommended for use in patients under the age of 18 years.

Do not use PegIntron:

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

Take special care with PegIntron:

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

Driving and using machines:

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE PEGINTRON

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

Combination treatment

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

PegIntron alone:

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

All patients:

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to use the PegIntron pre-filled pen).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. PegIntron is intended for single use only. Thus, after you give yourself the injection, discard the PegIntron pre-filled pen with any solution that is left in it.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

If you use more PegIntron than you should:

Tell your doctor or healthcare professional as soon as possible.

If you forget to take PegIntron:

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; convulsion ("fit"); trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyes or your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PEGINTRON

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the reconstituted solution.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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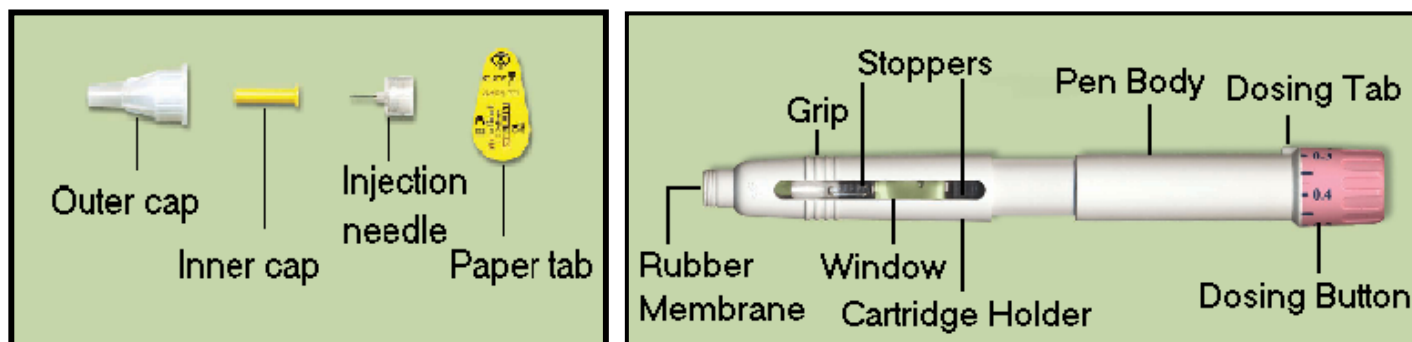
Italia

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This leaflet was last approved on

ANNEX TO THE PACKAGE LEAFLET

How to use the PegIntron pre-filled pen



The following instructions explain how to inject yourself with the single use PegIntron pre-filled pen. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you on how to self-inject with the PegIntron pre-filled pen. Do not attempt to inject yourself unless you are sure you understand the procedure and requirements for self-injection.

The PegIntron pre-filled pen is intended for use by one person only and must not be shared. Use the injection needle and cleansing swabs provided in the packaging only for the PegIntron pre-filled pen. Be sure the solution is at room temperature at the time of injection. Your doctor will have told you what dose you require for your therapy.

Note: The colour of the dosing button is different for each strength of the PegIntron pre-filled pen.

Step 1: Mixing

It is important that you keep the PegIntron pre-filled pen upright (as shown in figure 1) during mixing, unless otherwise instructed.

- Take the PegIntron pre-filled pen out of the refrigerator. Allow the medicine to come to room temperature.



Figure 1

- Wash your hands with soap and water.
- **Place the PegIntron pre-filled pen upright** in the holder of the tray provided in the pack (the dosing button will be on the bottom).
- You may want to hold the pre-filled pen using the grip. To mix the powder and the liquid, press the two halves together firmly by pressing down until you hear the pre-filled pen click. The two stoppers should come together.
- Wait for several seconds until the powder is completely dissolved.
- **Gently turn the PegIntron pre-filled pen upside down twice. To avoid excessive foaming, do not shake.**
- Maintaining the PegIntron pre-filled pen upright, check the mixed PegIntron solution through the window. If there is still foam, wait until it settles. **Do not use the pen if the solution is discoloured or contains any particles.**



Figure 2

- Keeping the PegIntron pre-filled pen upright in the holder provided in the packaging, disinfect the rubber membrane of the PegIntron pre-filled pen with one cleansing swab.
- Remove the protective paper tab from the injection needle.
- **Maintaining the PegIntron pre-filled pen upright in the holder**, gently push the injection needle onto the pre-filled pen and screw it securely in place.

- **Keep the PegIntron pre-filled pen pointed up.**
- **Do not take off the outer needle cap at this point.**
- You may see some liquid trickle out from under the cap, as the air has been expelled out of the pen.
- Wait about 5 seconds for this process to finish.

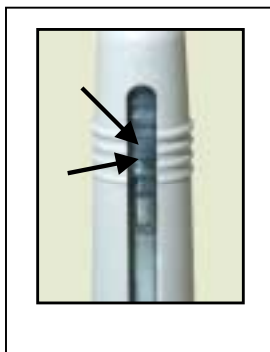


Figure 3

- **Check through the window to be sure that the two stoppers are together. If they are not together, do not use this pen because you may not be able to dial your dose.**

Step 2: Setting the dose



Figure 4

- Remove the PegIntron pre-filled pen from the holder.
- Holding the PegIntron pre-filled pen firmly, pull the dosing button out as far as it will go, until you see a dark ring on the pen. The dosing button should be easy to pull out without excessive force being required.

Note: Do not push the dosing button back in at this time. You will push it in when you are ready to self-inject the PegIntron.



Figure 5

- Turn the dosing button until your prescribed dose is aligned with the dosing tab. The button should turn easily without excessive force being required.

Note: If you cannot easily pull out the dosing button or dial the dose, do not use excessive force and do not use this pen because it may not deliver the correct dose.

Step 3: Injecting the solution

- Select the injection site. Your doctor will have told you which sites to use (e.g., thigh or abdomen).

Note: change your injection site each time.

- Clean the injection site skin with the second cleansing swab.



Figure 6

- Pull off the outer needle cap.
- There may be some liquid around the inner needle cap. This liquid is not part of your dose, this is extra. This is normal, as the air has been expelled out of the needle.
- Once the injection site is dry, pull off the inner needle cap carefully exposing the injection needle.



Figure 7

- Hold the PegIntron pre-filled pen with your fingers wrapped around the barrel and your thumb on the dosing button.
- With your other hand, pinch a fold of loose skin.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until the button can no longer move.
- Maintain pressure on the dosing button for an additional 5 seconds to ensure that you get the complete dose.

- Remove the needle from your skin.
- Press the injection site with a small bandage or sterile gauze if necessary for a few seconds.
- Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.
- Discard the PegIntron pre-filled pen with the needle safely in a closed rigid container.

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

PegIntron 120 micrograms powder and solvent for solution for injection in pre-filled pen
Peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 120 micrograms/0.5 ml.
- The other ingredients are:
Powder: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80;
Solvent: water for injections

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR

The pharmaceutical form is: powder and solvent for solution for injection.

The powder and solvent are both contained in a two-chamber glass cartridge assembled into a single use pre-filled pen.

PegIntron 120 micrograms is available in different pack sizes:

- 1 pen containing powder and solvent for solution for injection, 1 injection needle and 2 cleansing swabs;
- 4 pens containing powder and solvent for solution for injection, 4 injection needles and 8 cleansing swabs;
- 6 pens containing powder and solvent for solution for injection, 6 injection needles and 12 cleansing swabs;
- 12 pens containing powder and solvent for solution for injection, 12 injection needles and 24 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

2. BEFORE YOU USE PEGINTRON

PegIntron is not recommended for use in patients under the age of 18 years.

Do not use PegIntron:

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

Take special care with PegIntron:

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

Driving and using machines:

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE PEGINTRON

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

Combination treatment

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

PegIntron alone:

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

All patients:

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to use the PegIntron pre-filled pen).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. PegIntron is intended for single use only. Thus, after you give yourself the injection, discard the PegIntron pre-filled pen with any solution that is left in it.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

If you use more PegIntron than you should:

Tell your doctor or healthcare professional as soon as possible.

If you forget to take PegIntron:

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; convulsion ("fit"); trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyes or your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

Other common side effects that may occur with combination treatment are increased sweating, chest pain, pain on the right side around your ribs, numbness or tingling feeling, change in thyroid gland activity (which may make you feel tired or, less commonly, energetic), constipation, stomach upset, rapid heart rate, agitation, nervousness, difficult or irregular menstrual period, stuffy or runny nose, change in taste, blurred vision.

Less common are pain at the place of injection, flushing, low or high blood pressure, dry or teary eyes, redness of skin or skin disorder, feeling unwell, feeling faint, confusion, increased or decreased sensitivity to touch, tense muscles, loss of interest in sex, shaky hands, vertigo (spinning feeling), intestinal gas (flatus), bleeding gums or sores in mouth, changes in hearing or ringing in ears, thirst, aggressive behaviour, feeling sleepy, fever blisters, fungal infections, irritation of prostate gland, ear or respiratory infections, sinusitis, abnormal hair texture, sensitivity to sunlight, migraine headache, eye pain or infection, and swollen glands.

Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

When PegIntron is used alone, some of these effects are less likely to occur, and some have not occurred at all.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PEGINTRON

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).

Do not use after the expiry date stated on the carton.

After reconstitution, use the reconstituted solution immediately or within 24 hours when stored at 2°C - 8°C (in a refrigerator).

Do not use PegIntron if you notice discolouration of the reconstituted solution.

6. FURTHER INFORMATION

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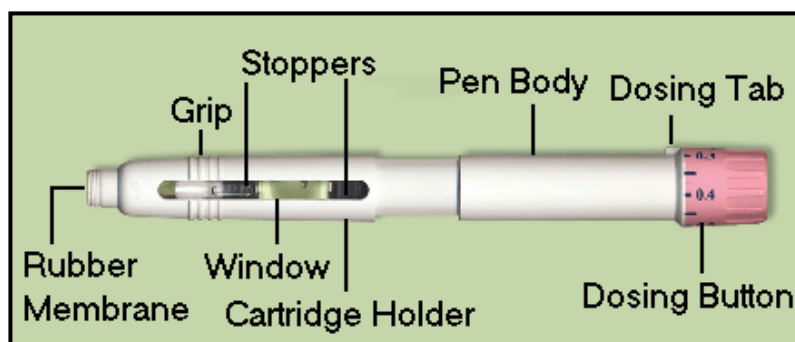
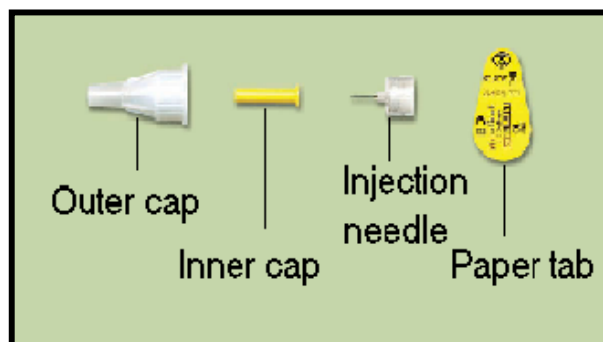
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ANNEX TO THE PACKAGE LEAFLET

How to use the PegIntron pre-filled pen



The following instructions explain how to inject yourself with the single use PegIntron pre-filled pen. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you on how to self-inject with the PegIntron pre-filled pen. Do not attempt to inject yourself unless you are sure you understand the procedure and requirements for self-injection.

The PegIntron pre-filled pen is intended for use by one person only and must not be shared. Use the injection needle and cleansing swabs provided in the packaging only for the PegIntron pre-filled pen. Be sure the solution is at room temperature at the time of injection. Your doctor will have told you what dose you require for your therapy.

Note: The colour of the dosing button is different for each strength of the PegIntron pre-filled pen.

Step 1: Mixing

It is important that you keep the PegIntron pre-filled pen upright (as shown in figure 1) during mixing, unless otherwise instructed.

- Take the PegIntron pre-filled pen out of the refrigerator. Allow the medicine to come to room temperature.



Figure 1

- Wash your hands with soap and water.
- **Place the PegIntron pre-filled pen upright** in the holder of the tray provided in the pack (the dosing button will be on the bottom).
- You may want to hold the pre-filled pen using the grip. To mix the powder and the liquid, press the two halves together firmly by pressing down until you hear the pre-filled pen click. The two stoppers should come together.
- Wait for several seconds until the powder is completely dissolved.
- **Gently turn the PegIntron pre-filled pen upside down twice. To avoid excessive foaming, do not shake.**
- Maintaining the PegIntron pre-filled pen upright, check the mixed PegIntron solution through the window. If there is still foam, wait until it settles. **Do not use the pen if the solution is discoloured or contains any particles.**



Figure 2

- Keeping the PegIntron pre-filled pen upright in the holder provided in the packaging, disinfect the rubber membrane of the PegIntron pre-filled pen with one cleansing swab.
- Remove the protective paper tab from the injection needle.
- **Maintaining the PegIntron pre-filled pen upright in the holder**, gently push the injection needle onto the pre-filled pen and screw it securely in place.

- **Keep the PegIntron pre-filled pen pointed up.**
- **Do not take off the outer needle cap at this point.**
- You may see some liquid trickle out from under the cap, as the air has been expelled out of the pen.
- Wait about 5 seconds for this process to finish.

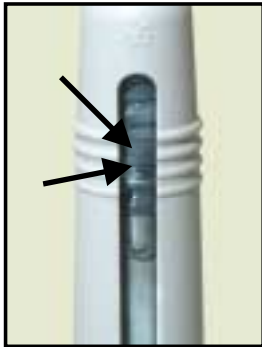


Figure 3

- **Check through the window to be sure that the two stoppers are together. If they are not together, do not use this pen because you may not be able to dial your dose.**

Step 2: Setting the dose



Figure 4

- Remove the PegIntron pre-filled pen from the holder.
- Holding the PegIntron pre-filled pen firmly, pull the dosing button out as far as it will go, until you see a dark ring on the pen. The dosing button should be easy to pull out without excessive force being required.

Note: Do not push the dosing button back in at this time. You will push it in when you are ready to self-inject the PegIntron.



Figure 5

- Turn the dosing button until your prescribed dose is aligned with the dosing tab. The button should turn easily without excessive force being required.

Note: If you cannot easily pull out the dosing button or dial the dose, do not use excessive force and do not use this pen because it may not deliver the correct dose.

Step 3: Injecting the solution

- Select the injection site. Your doctor will have told you which sites to use (e.g., thigh or abdomen).

Note: change your injection site each time.

- Clean the injection site skin with the second cleansing swab.



Figure 6

- Pull off the outer needle cap.
- There may be some liquid around the inner needle cap. This liquid is not part of your dose, this is extra. This is normal, as the air has been expelled out of the needle.
- Once the injection site is dry, pull off the inner needle cap carefully exposing the injection needle.



Figure 7

- Hold the PegIntron pre-filled pen with your fingers wrapped around the barrel and your thumb on the dosing button.
- With your other hand, pinch a fold of loose skin.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until the button can no longer move.
- Maintain pressure on the dosing button for an additional 5 seconds to ensure that you get the complete dose.

- Remove the needle from your skin.
- Press the injection site with a small bandage or sterile gauze if necessary for a few seconds.
- Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.
- Discard the PegIntron pre-filled pen with the needle safely in a closed rigid container.

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What PegIntron is and what it is used for
2. Before you use PegIntron
3. How to use PegIntron
4. Possible side effects
5. Storing PegIntron
6. Further information

PegIntron 150 micrograms powder and solvent for solution for injection in pre-filled pen
Peginterferon alfa-2b (conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol)

- The active substance is peginterferon alfa-2b, 150 micrograms/0.5 ml.
- The other ingredients are:
Powder: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80;
Solvent: water for injections

Marketing Authorisation Holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

Manufacturer: SP (Brinny) Company, Innishannon, County Cork, Ireland

1. WHAT PEGINTRON IS AND WHAT IT IS USED FOR

The pharmaceutical form is: powder and solvent for solution for injection.

The powder and solvent are both contained in a two-chamber glass cartridge assembled into a single use pre-filled pen.

PegIntron 150 micrograms is available in different pack sizes:

- 1 pen containing powder and solvent for solution for injection, 1 injection needle and 2 cleansing swabs;
- 4 pens containing powder and solvent for solution for injection, 4 injection needles and 8 cleansing swabs;
- 6 pens containing powder and solvent for solution for injection, 6 injection needles and 12 cleansing swabs;
- 12 pens containing powder and solvent for solution for injection, 12 injection needles and 24 cleansing swabs.

Not all pack sizes may be marketed.

Interferons modify the response of the body's immune system to help fight infections and severe diseases. PegIntron, which contains an interferon, is used for the treatment of chronic hepatitis C, a viral infection of the liver.

PegIntron is best used for this treatment in combination with ribavirin.

PegIntron is used alone in case of intolerance or contraindication to ribavirin.

2. BEFORE YOU USE PEGINTRON

PegIntron is not recommended for use in patients under the age of 18 years.

Do not use PegIntron:

- If you are hypersensitive (allergic) to peginterferon alfa-2b or any of the other ingredients of PegIntron.
- If you are hypersensitive (allergic) to any interferon.
- If you are pregnant or breast feeding.
- If you have had a severe nervous or mental disorder, especially if you have been very depressed or have thought about suicide, or tried to harm yourself.
- If you have had severe heart problems, or if you have heart disease that has not been well controlled during the past 6 months.
- If you have severe medical conditions that leave you very weak, including severe kidney disease.
- If you have autoimmune hepatitis or any other problem with your immune system; if you are taking medicine that suppresses your immune system (your immune system protects you against infection and some diseases).
- If you have advanced, uncontrolled liver disease (other than hepatitis C).
- If you have thyroid disease that is not well controlled with medicines.
- If you have a condition that causes convulsions (seizures, or “fits”).

Take special care with PegIntron:

- If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, or hives) while on this medication, seek medical help immediately.
- If you ever had a heart attack or a heart problem.
- If you have ever been treated for depression or any other nervous or mental disorder.
- If you have had a problem with your liver (other than hepatitis C).
- If you develop symptoms associated with a cold or other respiratory infection, such as fever, cough, or any difficulty in breathing, tell your doctor.
- If you are diabetic, your doctor may ask you to have an eye examination.
- If you have had any serious illness affecting your breathing or your blood.
- If you have psoriasis, it may become worse while you are using PegIntron.
- If you are planning to become pregnant, discuss this with your doctor before starting to use PegIntron.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Do not use PegIntron during pregnancy. The effect on human pregnancy is not known.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether this product is present in human milk. Therefore, do not breast-feed an infant if you are taking PegIntron.

Driving and using machines:

Do not drive or operate any tools or machines if you feel tired, sleepy or confused while taking PegIntron.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE PEGINTRON

Your doctor has prescribed PegIntron specifically for you and your current condition; do not share this medicine with anyone else.

Your doctor has determined your dose of PegIntron based on your weight. If necessary, the dose may be changed during treatment.

Combination treatment

PegIntron, when given with ribavirin capsules, is usually given at a dose of 1.5 microgram/kg once a week.

Ribavirin capsules are taken every day, morning and evening. The number of ribavirin capsules you take depends on your weight.

- If you weigh less than 65 kg, take 2 capsules in the morning and 2 in the evening (total of 800 mg each day).
- If you weigh between 65 and 85 kg, take 2 capsules in the morning and 3 in the evening (total of 1,000 mg each day).
- If you weigh more than 85 kg, take 3 capsules in the morning and 3 in the evening (total 1,200 mg each day).

The combination treatment is continued for at least 6 months, and sometimes for one year.

PegIntron alone:

PegIntron, when given alone, is usually given at a dose of 0.5 or 1.0 microgram/kg once a week, for at least 6 months, and possibly for 1 year.

All patients:

If you are injecting PegIntron yourself, please be sure that the dose that has been prescribed for you is clearly provided on the package of medicine you receive.

If you have the impression that the effect of PegIntron is too strong or too weak, talk to your doctor or pharmacist.

PegIntron is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. If you are injecting this medicine yourself, you will be instructed how to prepare and give the injection. Detailed instructions for subcutaneous administration are provided with this leaflet (see How to use the PegIntron pre-filled pen).

Prepare the dose just before you intend to inject it and use it immediately. Look carefully at the reconstituted solution prior to administration. Do not use if discolouration of the reconstituted solution is present. PegIntron is intended for single use only. Thus, after you give yourself the injection, discard the PegIntron pre-filled pen with any solution that is left in it.

Inject PegIntron once each week on the same day. Injecting it at the same time of day each week will help you not to forget to take it.

Use PegIntron exactly as prescribed by your doctor. Do not exceed the recommended dosage, and take it for as long as prescribed.

If you use more PegIntron than you should:

Tell your doctor or healthcare professional as soon as possible.

If you forget to take PegIntron:

Take the dose as soon as you remember, then continue your treatment as usual.

Do not take a double dose to make up for forgotten individual doses. Contact your doctor or pharmacist if needed.

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Like all medicines, PegIntron can have side effects. Although not all of these side effects may occur, they may need medical attention if they do.

Check with your doctor immediately if any of the following side effects occur: chest pain; changes in the way your heart beats; breathing problems, confusion; feeling depressed, wanting to harm yourself, numbness or tingling feeling; convulsion ("fit"); trouble sleeping, thinking or concentrating; severe stomach pain; fever or chills beginning after a few weeks of treatment, pain in your lower back or side; problems with your eyes or your eyesight or hearing; severe bleeding from your nose; your doctor will test your blood to ensure that your white blood cell (cells that fight infection) count and platelets (blood clotting cells) are at acceptable levels.

The most common side effects with the combination of PegIntron and ribavirin capsules are irritation or redness at the site of injection, headache, tired feeling, shaking chills, fever, flu-like symptoms, weakness, loss of weight, nausea, loss of appetite, diarrhoea or loose stools, stomach pain, vomiting, muscle aches, pain in joints and muscles, feeling depressed, irritability, trouble falling asleep or staying asleep, feeling anxious or nervous, difficulty concentrating, mood swings, hair loss, itching, dry skin, sore throat, coughing, difficult breathing, dizziness, virus infection, rash, and dry mouth.

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Very rarely sarcoidosis (a disease characterised by persistent fever, weight loss, joint pain and swelling, skin lesions and swollen glands) has been reported. Check with your doctor immediately if you have any of these symptoms.

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Keep out of the reach and sight of children.

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Do not use after the expiry date stated on the carton.

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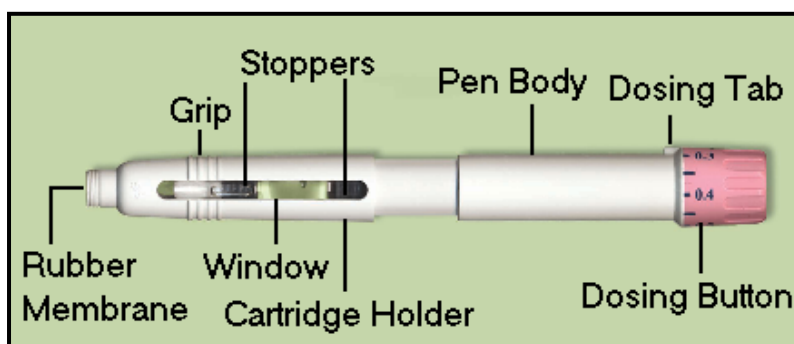
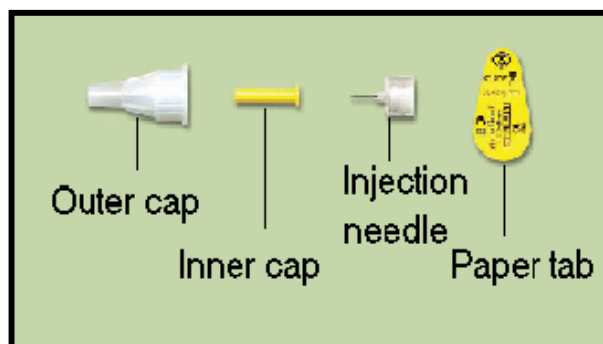
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ANNEX TO THE PACKAGE LEAFLET

How to use the PegIntron pre-filled pen



The following instructions explain how to inject yourself with the single use PegIntron pre-filled pen. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct you on how to self-inject with the PegIntron pre-filled pen. Do not attempt to inject yourself unless you are sure you understand the procedure and requirements for self-injection.

The PegIntron pre-filled pen is intended for use by one person only and must not be shared. Use the injection needle and cleansing swabs provided in the packaging only for the PegIntron pre-filled pen. Be sure the solution is at room temperature at the time of injection. Your doctor will have told you what dose you require for your therapy.

Note: The colour of the dosing button is different for each strength of the PegIntron pre-filled pen.

Step 1: Mixing

It is important that you keep the PegIntron pre-filled pen upright (as shown in figure 1) during mixing, unless otherwise instructed.

- Take the PegIntron pre-filled pen out of the refrigerator. Allow the medicine to come to room temperature.



Figure 1

- Wash your hands with soap and water.
- **Place the PegIntron pre-filled pen upright** in the holder of the tray provided in the pack (the dosing button will be on the bottom).
- You may want to hold the pre-filled pen using the grip. To mix the powder and the liquid, press the two halves together firmly by pressing down until you hear the pre-filled pen click. The two stoppers should come together.
- Wait for several seconds until the powder is completely dissolved.
- **Gently turn the PegIntron pre-filled pen upside down twice. To avoid excessive foaming, do not shake.**
- Maintaining the PegIntron pre-filled pen upright, check the mixed PegIntron solution through the window. If there is still foam, wait until it settles. **Do not use the pen if the solution is discoloured or contains any particles.**

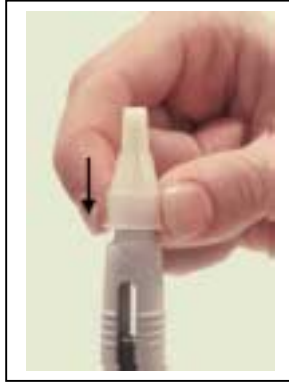


Figure 2

- Keeping the PegIntron pre-filled pen upright in the holder provided in the packaging, disinfect the rubber membrane of the PegIntron pre-filled pen with one cleansing swab.
- Remove the protective paper tab from the injection needle.
- **Maintaining the PegIntron pre-filled pen upright in the holder**, gently push the injection needle onto the pre-filled pen and screw it securely in place.

- **Keep the PegIntron pre-filled pen pointed up.**
- **Do not take off the outer needle cap at this point.**
- You may see some liquid trickle out from under the cap, as the air has been expelled out of the pen.
- Wait about 5 seconds for this process to finish.

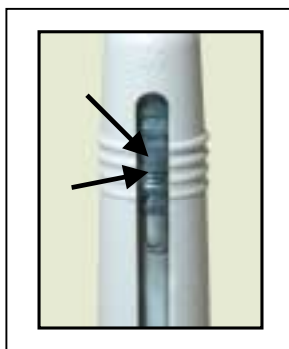


Figure 3

- **Check through the window to be sure that the two stoppers are together. If they are not together, do not use this pen because you may not be able to dial your dose.**

Step 2: Setting the dose



Figure 4

- Remove the PegIntron pre-filled pen from the holder.
- Holding the PegIntron pre-filled pen firmly, pull the dosing button out as far as it will go, until you see a dark ring on the pen. The dosing button should be easy to pull out without excessive force being required.

Note: Do not push the dosing button back in at this time. You will push it in when you are ready to self-inject the PegIntron.



Figure 5

- Turn the dosing button until your prescribed dose is aligned with the dosing tab. The button should turn easily without excessive force being required.

Note: If you cannot easily pull out the dosing button or dial the dose, do not use excessive force and do not use this pen because it may not deliver the correct dose.

Step 3: Injecting the solution

- Select the injection site. Your doctor will have told you which sites to use (e.g., thigh or abdomen).

Note: change your injection site each time.

- Clean the injection site skin with the second cleansing swab.



Figure 6

- Pull off the outer needle cap.
- There may be some liquid around the inner needle cap. This liquid is not part of your dose, this is extra. This is normal, as the air has been expelled out of the needle.
- Once the injection site is dry, pull off the inner needle cap carefully exposing the injection needle.



Figure 7

- Hold the PegIntron pre-filled pen with your fingers wrapped around the barrel and your thumb on the dosing button.
- With your other hand, pinch a fold of loose skin.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until the button can no longer move.
- Maintain pressure on the dosing button for an additional 5 seconds to ensure that you get the complete dose.

- Remove the needle from your skin.
- Press the injection site with a small bandage or sterile gauze if necessary for a few seconds.
- Do not massage the injection site. If there is bleeding, cover with an adhesive bandage.
- Discard the PegIntron pre-filled pen with the needle safely in a closed rigid container.